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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

PACIRA BIOSCIENCES, INC.,

Plaintiff,

v.

AMERICAN SOCIETY OF  
ANESTHESIOLOGISTS, INC.,  
EVAN D. KHARASCH, NASIR  
HUSSAIN, RICHARD BRULL,  
BRENDAN SHEEHY, MICHAEL K.  
ESSANDOH, DAVID L. STAHL,  
TRISTAN E. WEAVER, FARAJ W.  
ABDALLAH, BRIAN M. ILFELD,  
JAMES C. EISENACH, RODNEY A.  
GABRIEL, AND MARY ELLEN  
McCANN,

Defendants.

Civil Action No. 21-cv-9264-MCA-JSA

ECF Case

**REPLY MEMORANDUM OF LAW  
IN SUPPORT OF DEFENDANTS'  
MOTION TO DISMISS**

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## INTRODUCTION

Pacira's lengthy opposition disputes Defendants' scientific conclusions about EXPAREL but fails to refute the First Amendment principles that foreclose its claim.

**First**, Pacira nowhere addresses the many cases that hold that scientific conclusions published in peer-reviewed publications are inactionable as a matter of law, except where the underlying data was fabricated. Instead, Pacira asks the Court to credit the opinions of its experts about EXPAREL in its since-withdrawn preliminary injunction motion. But federal courts do not exist to referee scientific debates. That is the province of the scientific community, and one of the reasons journals such as *Anesthesiology* exist. Pacira's declarations, which in any event are irrelevant for pleading purposes, cannot cure the claim's *legal* defects.

**Second**, Pacira fails to adequately allege falsity. Instead, it points to its declarations to argue that Defendants should have used different methodologies to reach different conclusions. That is irrelevant to a trade libel claim. Pacira cannot dispute that Defendants fully disclosed the methodologies and data on which their conclusions were based. Well-established law—which Pacira ignores—precludes a finding of falsity as to such scientific studies, even if other scientists might reach other conclusions. That Pacira's own expert acknowledged that its scandalously-expensive form of bupivacaine fails to deliver a clinically-significant benefit over standard bupivacaine<sup>1</sup> only underscores its failure to properly plead falsity.

**Third**, Pacira's assertions of disagreements among scientists do not suffice to plead actual malice. Neither allegations that Defendants' analyses contained errors nor distorted assertions of undisclosed conflicts (which Defendants dispute) satisfy Pacira's obligation to show Defendants' published the challenged statements with actual knowledge of their falsity.

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<sup>1</sup> See Trikalinos Decl., Dkt. 3-3, at 24, ¶ 2 (showing that, after all methodological adjustments, EXPAREL's "revised" *statistical* value falls below the 2.0 threshold for *clinical* significance).

*Fourth*, Pacira’s vague allegations of lost sales fail to meet its burden to plead the loss of specific customers as a result of Defendants’ articles, particularly given its CFO’s public statements that doctors have not changed their EXPAREL practices in response to those articles.

These defects cannot be cured. The Court should dismiss this lawsuit with prejudice.

## **ARGUMENT**

### **I. PACIRA FAILS TO REFUTE THAT IT IS ATTACKING INACTIONABLE SCIENTIFIC CONCLUSIONS**

Pacira does not dispute that, “[a]s a matter of law, statements of scientific conclusions about unsettled matters of scientific debate cannot give rise to liability for damages sounding in defamation.” Br. 10 (quoting *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490, 492 (2d Cir. 2013)).<sup>2</sup> Nor does Pacira dispute that the challenged statements are such “scientific conclusions” or deny the general presumption against subjecting academic works published in a peer-reviewed journal to judicial scrutiny. Instead, Pacira insists—without legal support—that the challenged statements are nonetheless actionable because they “state or imply false underlying facts” about the clinical efficacy of EXPAREL. Opp. 18.

But *ONY* and its progeny held otherwise: “While statements about contested and contestable scientific hypotheses constitute assertions about the world that are in principle matters of verifiable ‘fact,’ for purposes of the First Amendment and the laws relating to ... defamation, they are more closely akin to matters of opinion.” *ONY*, 720 F.3d at 497. That the

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<sup>2</sup> Pacira does not attempt to distinguish *ONY* because it cannot: As here, plaintiffs challenged scientific conclusions published in a peer-reviewed article “about the relative effectiveness” of a drug on the grounds that the article’s scientific methodology omitted data, that this omission was “intentional and designed to mask” a contrary scientific conclusion, that the authors “fail[ed] to cite articles with different primary conclusions,” that the article improperly selected data, and that there was a conflict of interest underlying the study. *Id.* at 494–95. *ONY* concluded that “the contents of the article are non-actionable scientific conclusions to which ... [the] common law tort of injurious falsehood [does not] apply.” *Id.* at 498.

challenged statements appear to be “propositions of empirical ‘fact’” does not render them actionable because, “[i]n a sufficiently novel area of research,” such statements are understood to be opinion because they are “highly controversial and subject to rigorous debate by qualified experts.” *Id.* And matters of opinion, of course, are inactionable. *Id.* Pacira’s repeated invocation of its withdrawn expert reports (Opp. 19–26), which reach different conclusions on the efficacy of EXPAREL and the propriety of the authors’ methodology and conclusions, confirm that Pacira’s trade libel claim falls squarely within this realm of inactionable opinion.

Unable to counter this authority, Pacira assert that “Defendants do not appear to dispute that the statements Pacira identifies as false could be construed as defamatory.” Opp. 17. But Defendants disputed exactly that, because Pacira has challenged as false only the conclusions the scientists reached, not the accuracy of the report of the underlying data. Br. 12–17; Opp. 24 (referring to “conclusion” that EXPAREL is “not superior”); Opp. 27. Pacira asserts, for example, that the articles’ conclusions “falsely imply that a comprehensive and unbiased review” occurred. Opp. 27. But as *ONY* and its progeny made clear, these conclusions are not defamatory because they “are ... available to other scientists who may respond by attempting to replicate the described experiments, conducting their own experiments, or analyzing or refuting the soundness of the experimental design or the validity of the inferences drawn from the result.” 720 F.3d at 497; *see* Opp. 22–24 (detailing methodological disagreements with the authors’ meta-analysis). The proper forum for such a dispute is “in the pages of peer-reviewed journals,” not the courthouse. *ONY*, 720 F.3d at 497; *see also Biolase, Inc. v. Fotona Proizvodnja Optoelektronskih Naprav D. D.*, 2014 WL 12579802, at \*5 (C.D. Cal. June 4, 2014).<sup>3</sup>

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<sup>3</sup> Pacira cites three cases for the general rule that verifiable statements are actionable. Opp. 17–18. Those cases do not address the unique nature of scientific conclusions, which necessarily

Read charitably, Pacira addresses *ONY* (Opp. 19) only by suggesting that its claims may proceed under a narrow exception for falsification of underlying data. *See ONY*, 720 F.3d at 497 (“[I]t is relevant that plaintiff does not allege that the data presented in the article were fabricated or fraudulently created.”). But Pacira does not (and cannot) allege that the Defendant authors “fabricated or fraudulently created” the data on which they relied.

Instead, Pacira asserts that the meta-analysis and cover of the February 2021 issue state unfairly that liposomal bupivacaine is “not superior” to standard analgesics without qualifying that conclusion, despite EXPAREL’s purported extended duration. Opp. 19. But Pacira misrepresents the Hussain article, which expressly identified “notable limitations” in its review, *see* Br. 21, including that its methodology did not involve an “individual timepoint analysis.” Compl. Ex. 1, Hussain Meta-Analysis at 12. *ONY* expressly recognized the importance of such qualifications in holding that such scientific conclusions are not actionable statements of fact. 720 F.3d at 494 (“The article’s conclusions were not unqualified. The authors considered [an objection that] might cause a disparity between the groups included in the study...”)<sup>4</sup> Even so, Pacira’s allegation that “the inferences drawn from those data were the wrong ones” does not render the statements actionable: “the validity of the authors’ conclusions may be assessed on their face by other members of the relevant discipline or specialty.” *Id.* at 497–98; Br. 14–15.

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“are tentative and subject to revision” even when presented as verifiable fact. *ONY*, 720 F.3d at 496. *Cf. Mayflower Transit, LLC v. Prince*, 314 F. Supp. 2d 362, 373 (D.N.J. 2004) (concerning customer’s review of moving company); *Wolfe v. Gooding & Co., Inc.*, 2017 WL 3977920, at \*3 (D.N.J. Sept. 11, 2017) (concerning origins of a car frame); *Mangan v. Corp. Synergies Grp., Inc.*, 834 F. Supp. 2d 199, 205 (D.N.J. 2011) (concerning statements about financial records).

<sup>4</sup> Pacira relatedly asserts that the conclusion that EXPAREL is “not superior” cannot rest on a finding that it does not provide a clinically important improvement in pain management because the finding is at best “equivocal.” Opp. 20. But a drug that does not provide a clinical benefit—particularly one that costs 100 times more than the alternative—is, by definition, “not superior” to that alternative. Br. 7.



Pacira next argues that the authors of the Hussain Meta-Review should have considered the procedures performed in the underlying studies and failed to disclose that “the benefits of EXPAREL depend, in part, on the surgical procedure for which it is used.” Opp. 20–21. Again, Pacira appears not to have read the article, which expressly discloses as the first “notable limitation[.]” that the authors examined “a variety of surgical procedures and block techniques,” in a manner that could “limit the external validity of our results and limit their broad applicability.” Hussain Meta-Review at 12; Br. 21. And were Pacira’s criticism valid, it would amount to the very claim that *ONY* held inactionable—“that competent scientists would have included variables ... that were not taken into account.” *ONY*, 720 F.3d at 497; Br. 13. The same holding forecloses Pacira’s claim premised on the more general assertion that the “authors cherry-picked studies to include,” (Opp. 21), because “the reliability of the data in [scientific] articles is not fit for resolution in the form of a defamation lawsuit.” *Saad v. Am. Diabetes Ass’n*, 123 F. Supp. 3d 175, 179 (D. Mass. 2015).<sup>5</sup>

Pacira further asserts that the Hussain Meta-Review improperly claimed “all estimates of the effect of EXPAREL were of high quality and characterized by low levels of heterogeneity” when one of its own expert reports concluded otherwise. Opp. 21. Such disagreements between experts about how to interpret data are legally insufficient to sustain claims sounding in defamation. *See ONY*, 720 F.3d at 497; *Padnes v. Scios Nova Inc.*, 1996 WL 539711 (N.D. Cal. Sept. 18, 1996) (“Medical researchers may well differ ... as how best to interpret data.”).

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<sup>5</sup> Pacira also quibbles that it was inappropriate for the Hussain Meta-Analysis to claim low levels of heterogeneity when “the authors never tested for heterogeneity for ... the primary outcome examined.” Opp. 22. But the Hussain Meta-Analysis fully disclosed that it did not assess heterogeneity for pain scores, instead assigning heterogeneity values only for secondary outcomes. Hussain Meta-Analysis at 10. The statements concerning heterogeneity are thus inactionable as “authors readily disclosed ... potential shortcomings.” *ONY*, 720 F.3d at 498.

Finally, Pacira attacks the methodological decisions of the authors of the Hussain Meta-Review, including “crude pooling,” the application of a “Bonferroni-Holm” correction, a strict “confidence interval,” failing to employ “inverse-variance,” ignoring “correlations,” and imputing “the standard deviation.” Opp. 22–24. But Pacira does not (and cannot) allege that the Hussain Meta-Analysis hid these methodological determinations from its readers, and *ONY* and its progeny are clear that libel claims may not rest on allegations “that the methodologies used in the studies described in the scientific articles are unreliable.” *Biolase*, 2014 WL 12579802, at \*4; *ONY*, 2012 WL 1835671, at \*10 (“[P]erceived fault in the method ... should be subjected to peer review rather than judicial review.”); Br. 14.

Pacira’s arguments concerning the Ilfeld Review fail for the same reason: Pacira disputes the article’s “factual conclusion,” claims the author failed to consider what Pacira deems “the most relevant group of studies,” and criticizes the author’s dismissal of “industry-funded trials” and assessment of bias in the studies on which they do rely. Opp. 24–25. These challenges to the “experimental design or the validity of the inferences drawn from the results” are inactionable. *ONY*, 720 F.3d at 497. Pacira also asserts without authority that a libel claim concerning the Ilfeld Review may rest on the failure of two of the authors to disclose payments. The law is to the contrary. *See Biolase*, 2014 WL 12579802, at \*1 (dismissing claims despite allegation that “the authors of the articles don’t disclose their affiliation with [defendant]”). And such omissions cannot be libelous because they do not address EXPAREL. *See* Br. 15 n.10.

Pacira does not attempt to distinguish its allegations concerning the challenged statements in the CME Materials, McCann Editorial, and Podcast from those statements contained in the Hussain Meta-Analysis and Ilfeld Review. Opp. 27 (explaining those materials “contain or repeat many of the same false statements”). Nor could it, as Pacira affirmatively pled

that those materials “repeated the conclusions of both articles” and “restate as fact the various ... conclusions reached by the articles.” See Br. 15–16 (quoting Compl. ¶¶ 59–67).<sup>6</sup> Accordingly, Pacira’s trade libel claims as to the CME Materials, McCann Editorial, and Podcast fail because the underlying scientific conclusions that those materials restate are themselves inactionable opinion. See Br. 15–16; *ONY*, 720 F.3d at 499 (affirming dismissal of claims arising from materials that “present[] accurately [a scientific] article’s allegedly inaccurate conclusions”).

## II. A DISPUTE OVER METHODOLOGY IS NOT AN ALLEGATION OF FALSITY

Pacira argues that studies conducted according to its preferred approach would reach different conclusions, characterizing most of the allegedly false statements as scientific “errors” or improper “methodologies.” Opp. 22–23. But as a matter of law, such methodological quibbles and disagreements about scientific conclusions cannot establish falsity. Br. 18–19.

***Hussain Meta-Analysis:*** Pacira asserts that this includes a false statement because it “make[s] the blanket statement that liposomal bupivacaine is ‘not superior’ to standard analgesics, with no qualifying language.” Opp. 19–21. Even assuming that this should not be treated as a scientific conclusion, *see supra*, Pacira ignores the article’s prominent qualifying language, including the analysis’s expressly-acknowledged “notable limitations.” See Br. 21. Courts do not assess falsity based on such a selective presentation; instead, the “court must consider a statement as a whole to determine the impression it will make on a reader.” *Read v. Profeta*, 397 F. Supp. 3d 597, 651 (D.N.J. 2019); *see also* Br. 22.

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<sup>6</sup> Pacira argues that the McCann Editorial “goes further, implying that Pacira aggressively markets EXPAREL to line its pockets.” (Opp. 28–29) But Pacira does not (and cannot) claim that the piece misrepresents EXPAREL’s \$335 cost. See Br. 22. The remaining statements, such as what Pacira characterizes as an insinuation that customers purchase EXPAREL because of marketing (Opp. 29), are non-actionable opinion, as evinced by their placement in an *editorial*.

Moreover, the statement is not false even without that qualifying language. Pacira alleges only that: (1) some evidence shows EXPAREL provides pain relief for a longer period of time than alternatives; and (2) other research studies show EXPAREL provides a favorable alternative. Opp. 19–20. Neither is an allegation of falsity as to the subject articles. The meta-analysis does not purport to define superiority based on duration (and instead emphasizes that it considered rest pain scores over a “specific time interval (*i.e.*, 0 to 24 h, 25 to 48 h, 49 to 72 h).” Hussain Meta-Analysis at 3. Similarly, that Pacira’s expert “reached a different conclusion” when analyzing different studies is insufficient to “establish that [Defendants’] interpretation of the results were false or misleading.” *In re Adolor Corp. Sec. Litig.*, 616 F. Supp. 2d 551, 568 n.15 (E.D. Pa. 2009); Br. 21–22. As a matter of law, the meta-analysis’s statement regarding “levels of heterogeneity” is also not false merely because Pacira’s expert concluded differently.

The same is true of Pacira’s assertions that the meta-analysis should have included other studies or other variables in its review. Opp. 21. Such disputes cannot establish falsity. *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1225 (S.D. Cal. 2001) (concluding that “a legitimate difference in opinion as to the proper statistical analysis” does not render statements false); *In re Rigel Pharms.*, 697 F.3d 869, 878 (9th Cir. 2012) (allegations are “not about false statements” where “Plaintiff’s allegations of ‘falsity’ essentially are disagreements with the statistical methodology adopted by the doctors and scientists who designed and conducted the study, wrote the journal article, and selected the article for publication”); Br. 19–21.

***Ilfeld Review:*** Pacira’s allegations of falsity as to the Ilfeld Review also fail. The Ilfeld Review concludes that “Ninety-two percent of trials (11 of 12) suggested a peripheral nerve block with *unencapsulated* bupivacaine ...provides superior analgesia to infiltrated liposomal bupivacaine,” Ilfeld Review at 1 (emphasis added). Pacira again claims this conclusion is false.

Opp. 24. But Pacira does not (and could not) allege that the eleven trials conclude otherwise, foreclosing a finding of falsity. *See* Br. 21; *Rigel*, 697 F.3d at 878 (dismissing claim for lack of falsity where plaintiff does not allege “Defendants misrepresented the results they obtained”).

Instead, Pacira asserts the Ilfeld Review should have considered what Pacira terms “the most relevant group of studies” and other “industry funded trials.” Opp. 24–25. But allegations that scientists should have considered additional variables are insufficient as a matter of law to establish falsity. *DeMarco*, 149 F. Supp. 2d at 1225 (dismissing allegation for lack of falsity as “little more than hindsight-based criticism and speculation” where challenged analysis purportedly “does not properly ... take into account” certain variables); *see also* Br. 19–20.

Pacira also claims the Ilfeld Review contains false statements because the authors improperly applied the Cochrane risk-bias assessment framework and presented certain studies as having low risk of bias, contrary to the analysis performed by Pacira’s own expert that found those studies have substantial risk of bias. Opp. 26. That data is susceptible to competing statistical conclusion, however, “does not establish that [defendants’] interpretations of the results were false or misleading.” *Adolor*, 616 F. Supp. 2d at 568 n. 15; *see also* Br. 21–22.

***McCann Editorial And Supplemental Materials:*** Pacira alleges that statements made in the McCann Editorial, CME Activity, and Podcast were false because they “parrot[] many of the same false conclusions found in the Hussain and Ilfeld articles.” Opp. 28. These allegations cannot establish falsity for the same reason Pacira’s underlying claim about the conclusions in the Hussain and Ilfeld articles fails. *Supra* 7–9. Pacira also argues that the McCann Editorial implies that “Pacira aggressively markets EXPAREL to line its pockets,” “that the FDA approved EXPAREL with insufficient evidence, and that customers purchase EXPAREL only because of Pacira’s marketing.” Opp. 29. But Pacira does not even attempt to identify any

statements that are demonstrably false. Nor could it. *Lynch v. New Jersey Educ. Ass’n*, 161 N.J. 152, 167 (1999) (“Statements of opinion ... cannot be proved true or false.”)

### III. PACIRA FAILS TO REHABILITATE ITS ALLEGATIONS OF MALICE

Pacira acknowledges its need to plead that each speaker “knew the statement to be false or acted in reckless disregard of its truth or falsity.” Opp. 31. But without citation, Pacira claims such a showing is a “low bar,” Opp. 32. Not so. Even at the pleading stage, a “plaintiff has a high hurdle to clear to adequately allege actual malice.” *Earley v. Gatehouse Media Pennsylvania Holdings, Inc.*, 2015 WL 1163787, at \*3 (M.D. Pa. Mar. 13, 2015); *see also Pace v. Baker-White*, 432 F. Supp. 3d 495, 513–514 (E.D. Pa. 2020) (similar).

Pacira argues it has pled actual malice by alleging numerous errors in the articles and by alleging motive. Opp. 33–35. But Pacira makes no argument as to each Defendant’s knowledge or recklessness, which it must do. Br. 24. Moreover, as to the claimed “errors,” Pacira fails to allege more than carelessness, which supports a finding of only “negligence, not actual malice.” *Levesque v. Doocy*, 560 F.3d 82, 91 (1st Cir. 2009). Pacira recites allegations that Defendants violated “multiple industry standards” (Opp. 35), but ignores that even “extreme departure from professional standards fails to meet the actual malice standard.” Br. 26–27.<sup>7</sup> Nor are Pacira’s motive allegations—purportedly, conflicts of financial interests and pro-opioid biases (Opp.

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<sup>7</sup> Pacira’s cases are not to the contrary. *Medure v. New York Times Co.*, 60 F. Supp. 2d 477, 489 (W.D. Pa. 1999), held a plaintiff *failed* to demonstrate actual malice because, in part, “it is not the court’s role to second-guess ... editorial decisions,” thereby refuting Pacira’s allegations of malice based on the editorial decision to solicit the McCann Editorial. *Moore v. Vislosky*, 240 F. App’x 457, 468 (3d Cir. 2007), concerned a jury’s determination regarding a defendant’s refusal to produce documentation she said supported her statement. Similarly, *Schiavone Constr. Co. v. Time, Inc.*, 847 F.2d 1069, 1090 (3d Cir. 1988), concerned a defendant’s disregard of contradictory evidence from three highly credible FBI employees. And, in *Harte-Hanks Commc’ns, Inc. v. Connaughton*, 491 U.S. 657, 692 (1989), the Court held the jury verdict rested on sufficient evidence of reckless disregard for truth or falsity apart from the motive allegations.

34)—sufficient to allege actual malice. *Lynch*, 161 N.J. at 166–67 (“[D]eliberate intent to harm” is not “reckless disregard for its truth.”).

#### IV. PACIRA POINTS TO NO ALLEGATIONS OF SPECIAL DAMAGES

Even setting aside Pacira’s CFO statement that Pacira has not suffered harm, Br. 1, Pacira does not plead the “special damages” necessary for trade libel, which requires specific allegations linking named lost customers to the challenged libelous statements. *See* Br. 28–29.<sup>8</sup>

Pacira argues that its general and conclusory allegations of loss are adequate at the pleading stage. *Opp.* 37–38. But as the Third Circuit explained in affirming the dismissal of a claim for trade libel under New Jersey law, a plaintiff must allege loss of “specifically named patients” and connect those losses to the challenged statements. *Bocobo v. Radiology Consultants of S. Jersey, P.A.*, 477 F. App’x 890, 901 (3d Cir. 2012). Pacira pleaded only that “several ... existing customers have discontinued, or are threatening to discontinue, their use of EXPAREL.” Br. 29. Such wording is ambiguous as to whether Pacira lost even one customer.

#### V. LEAVE TO AMEND WOULD BE FUTILE

The Court should reject Pacira’s request for leave to amend because it would be futile. *See Shane v. Fauver*, 213 F.3d 113, 115 (3d Cir. 2000) (leave to amend inappropriate where “the amendment would not cure the deficiency”). The statements Pacira alleges to be false are inactionable scientific conclusions, as a matter of law. No additional detail can render Pacira’s allegations sufficient. *See ONY*, 2012 WL 1835671, at \*11 (denying leave to amend injurious falsehood claim as challenged scientific conclusions are inactionable as a matter of law); *Joseph*

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<sup>8</sup> Pacira claims its CFO told investors only that “the company is doing well.” *Opp.* 38. Not so. He said Pacira did not have “anything to worry about” from the articles because there was “clear separation” between the ASA and “doctors in the field” concerning use of EXPAREL. Br. 1.

*v. Springer Nature*, 2021 WL 1372952, at \*9 (S.D.N.Y. Apr. 12, 2021) (dismissing libel claim concerning scientific conclusions and denying leave to amend).

**CONCLUSION**

For the reasons set forth above and in Defendants' opening memorandum, the Court should dismiss the Complaint with prejudice.

Dated: July 12, 2021

Respectfully submitted,



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